DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 17 2007

Re: Gardasil
Docket No.: 2006E-0501

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,820,870, filed by Merck & Co., Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Gardasil (Quadrivalent Human Papillomavirus Recombinant Vaccine), the human biological product claimed by the patent.

The total length of the regulatory review period for Gardasil is 2,215 days. Of this time, 2,031 days occurred during the testing phase and 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: May 17, 2000.

   The applicant claims May 14, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 17, 2000, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 7, 2005.

   FDA has verified the applicant's claim that the biologics license application (BLA) for Gardasil (BLA 125126/0) was initially submitted on December 7, 2005.

3. The date the application was approved: June 8, 2006.

   FDA has verified the applicant's claim that BLA 125126/0 was approved on June 8, 2006.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Joanne M. Giesser
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